KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

510(k) Premarket Notification
Kendall 14.5 Fr. MAXID Cuffed Dual Lumen Catheter

Section H – 510(K) Summary

Date Summary Was Prepared: August 10, 2000

Submitter's Information:
The Kendall Company
15 Hampshire Street
Mansfield, MA 02048

Phone: 508-261-8000
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Contact:
Paul Evans
Director, Regulatory Affairs
The Kendall Company

Telephone: 508-261-8203
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Device Trade Name: Kendall 14.5 Fr. MAXID Cuffed Dual Lumen Catheter

Device Common Name: Catheter, Intravascular, Short-term and Long-term

Classification Panel: Gastroenterology

Legally Marketed Devices To Which Substantial Equivalence Is Claimed To: The Kendall 14.5 Fr MAXID Cuffed Dual Lumen Catheter is substantially equivalent to the Bard 14.5 Fr Vas-Cath Opti-Flow Dual Lumen Catheter, and the Kendall Mahurkar® 13.5 Fr Cuffed Dual Lumen Catheter.

Device Description:. The Kendall 14.5 Fr. MAXID Cuffed Dual Lumen Cuffed catheter is composed of a radiopaque polyurethane catheter shaft with two large lumens (arterial and venous) in a "Double D" configuration. The lumens are distinguishable by color-coded luer-lock adapters on clear silicone rubber extensions.

The distal end of the catheter extends to a staggered tip configuration. The catheter tip will be offered in two styles. One configuration will have five (5) side holes on the arterial outlet, and two (2) side holes on the venous outlet. The second tip configuration will be offered with no side holes.

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Intended Use: The Kendall 14.5 Fr MAXID Cuffed Dual Lumen Catheter is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown.

Technological Characteristics: The technological characteristics of the Kendall 14.5 Fr MAXID Cuffed Dual Lumen Catheter, including catheter type, intended use, insertion method, insertion sites, number of lumens and infusion flow rate performance are similar to the Bard Vas-Cath Opti-Flow Dual Lumen Catheter. The catheter's design, materials of construction, and mechanical characteristics are also similar to the Kendall 13.5 Fr Mahurkar Cuffed Dual Lumen catheter.

Performance Data: Performance data for the Kendall 14.5 Fr MAXID Cuffed Dual Lumen Catheter were compared to that of the predicate device identified in this 510(K) summary. These test results demonstrate that the device is substantially equivalent to the predicate device commercially distributed for the same intended use.

Paul W. Evans
Paul W. Evans
The Kendall Company

Sept. 15, 2000
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2001

Mr. Paul Evans
Director, Regulatory Affairs
The Kendall Company
15 Hampshire Street
Mansfield, MA 02048

Re: K002901
Kendall 14.5 Fr MAXID Cuffed Dual Lumen Catheter
Regulation Number: 876.5540
Regulatory Class: III
Product Code: 78 MSD
Dated: January 8, 2001
Received: January 9, 2001

Dear Mr. Evans:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used for the device. However, you should be aware of the following addition information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.

2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

In addition, we have determined that your device kit contains lidocaine, 1%, Povidone iodine swabsticks, and Povidone iodine ointment, 1g, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

Appendix 1

Indications for Use Statement

Device Name:

Kendall 14.5 Fr MAXID Cuffed Dual Lumen Catheter

Indications for Use:

The Kendall 14.5 Fr MAXID Cuffed Dual Lumen Catheter is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

David C. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002901